510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Sheila Bruschi
Associate Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121

Date Prepared: September 29, 2011

B. Device Name

Trade or Proprietary Name:	*NuVasive® Disposable Stimulating Electrode*
Common or Usual Name:	Nerve Stimulator/Locator
Classification Name:	Surgical Nerve Stimulator/Locator

Device Class:	Class II
Classification:	21 CFR § 874.1820
Product Code:	ETN

C. Predicate Devices

The subject *Disposable Stimulating Electrode* is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K103128 – Cadwell Disposable Stimulator Probe
- K090838 – Axon Systems Stimulus/dissection Instruments
- K031003 – Medtronic Xomed Stimulus / Dissection Instruments

D. Device Description

The *Disposable Stimulating Electrode* is a single-use; sterile stimulating electrode composed of polyphenylsulfone (PPSU) and a conductive silver. The *Disposable Stimulating Electrode* is insulated along its length with a dielectric coating, a non-insulated proximal connector to attach to any compatible neuromonitoring stimulator, and a non-insulated distal tip to deliver tissue stimulation.

E. Intended Use

The NuVasive *Disposable Stimulating Electrode* is indicated for tissue dissection and stimulation of spinal nerve roots for identification and location during surgery.

F. Technological Characteristics

As was established in this submission, the subject *Disposable Stimulating Electrode* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, pyrogenicity-labeling, and functions. The device is not labeled as non-pyrogenic. The shelf life of the device is

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *Disposable Stimulating Electrode* is substantially equivalent to other predicate devices. The following testing was performed:

- Impedance and Durability Testing
- Biocompatibility testing per:
  ISO 10993-1:2009, ISO 10993-10:2002/Amd. 1:2006(E),
  ISO 10993-11:2006, ISO 10993-5:2009
- Sterilization assessment and adoption per AAMI TIR 28: 2009
- Sterilization validation on a master device per ISO 11135-1: 2007
- Bioburden analysis per ISO 11737-1:2006
- EO sterilization residual analysis per ISO 10993-7:2008
- Shelf life validation per:

  ASTM F1980: 2007, ASTM D4332-01: 2006, ISO 11607: 2006,
  ASTM F2096: 2004, and ASTM F88:2009.

The results of these studies showed that the subject *Disposable Stimulating Electrode* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *Disposable Stimulating Electrode* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Inc.
c/o Ms. Sheila Bruschi
7475 Lusk Boulevard
San Diego, CA 92121

OCT 13 2011

Re: K111597
Trade/Device Name: Disposable Stimulating Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: September 20, 2011
Received: September 21, 2011

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111597

Device Name: *NuVasive® Disposable Stimulating Electrode*

Indications For Use:

The *NuVasive® Disposable Stimulating Electrode* is indicated for tissue dissection and stimulation of spinal nerve roots for identification and location during surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K111597